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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,720	09/29/2006	Isamu Koyama	740819-1160	9395

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EXAMINER	
SZPIRA, JULIE ANN	
ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
04/25/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@sbpatentlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,720	KOYAMA ET AL.	
	Examiner	Art Unit	
	JULIE A. SZPIRA	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2,4-7 and 10-12* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) *1, 2, 4-7 and 10-12* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 1, 4-7 and 10-12** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "a first guiding member configured to be inserted from an oral cavity into a pharynx prior insertion to the tubular member into the pharynx…". It is unclear as to what member is to be inserted into the pharynx in what order. The claim could be interpreted as being the first guiding member is inserted into the tubular member prior insertion into the pharynx, or the guiding member is introduced to the pharynx and then the tubular member is introduced. The claim requires clarification.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1, 2, 4-7 and 10** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nichols (US 3,088,466)** in view of **Jones (US 4,278,081),** further in view of **Toy (US 3,511,243).**

Regarding claims 1, 2 and 4-7, Nichols discloses a supporting device capable of supporting insertion of a medical instrument into a human body, comprising: a tubular member (1) includes a tubular member engagement section (15), the tubular member further includes an inner passageway between its opposite ends through which the medical instrument is capable of passing, wherein the tubular member is configured to guide the medical instrument into a digestive organ from an oral cavity through a pharynx, the tubular member is formed in a curved shape (Figure 1) in advance to conform to the shape of pharynx, and the tubular member has a diameter that is larger than that of the pharynx to allow an expansion of the pharynx; a guiding member (3) configured to be inserted from an oral cavity into a pharynx insertion to the tubular member into the pharynx, to guide the tubular member and the reinforcement member, during insertion thereof from the oral cavity and into the pharynx and to be removed from the pharynx and oral cavity while the tubular member remains inserted in the pharynx (column 4, lines 48-56), the guiding member includes a guiding member engagement section (13) and the guiding member has a diameter smaller than that of the inner passageway, and when inserted from an oral cavity into the pharynx and

retained there, the tubular member can guide the medical instrument to the digestive organ through the inner passageway, and such that when the guiding member engagement section is engaged with the tubular member engagement section, the digestive organ end of the guiding member is generally coincident with the digestive organ end of the tubular member (column 4, line 71-column 5, line 5), but fails to disclose the tubular member having a slanted distal end, containing a reinforcement element, a second guiding member and the diameter of the tubular member being greater than 20mm.

However, Jones teaches a tubular member with a slanted distal end, (Figure 2) molded to contain a spiral reinforcement element (70) therein that extends within the inner passageway along a longitudinal centerline, but does not extend past the distal end of the tubular member (column 7, line 66-column 8, line 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tubular member as disclosed by Nichols have a slanted distal end and including a spiral reinforcement member as taught by Jones to support the patency of the lumen of the tubular member, while still allowing a degree of flexibility, while reducing pressure at the distal end of the device (column 8, lines 3-7; the slanted end does not exert pressure 360° within the tubular organ at the distal end, thus relieving the pressure at that end).

Toy teaches a first guiding member (2) and a second guiding member (14) and a tubular member (10) that fits over the first and second guiding members (Figures 7-9),

wherein the tubular member diameter is greater than 20mm (column 3, lines 45-48; 2 inches is approximately 50mm).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention disclosed by Nichols in view of Jones to use two guiding tubes as taught by Toy to provide a gradual expansion of the lumen in which the device is placed (column 3, lines 20-31). The initial insertion of first guiding member (2) would dilating the lumen to a first diameter, second guiding member (14) would slightly enlarge that diameter and finally the tubular member would be the largest in diameter, fitting over both the first and second guiding member to enlarge the lumen to the final diameter.

The prior art of record does not specifically disclose the device being used to dilate a pharyngeal lumen, but it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Parte Masham, 2 USPQ F.2d 1647 (1987). The devices disclosed in the prior art have the structural capability of being used to dilate a pharynx. The dual guiding tubes disclosed by Toy are used to gradually dilate an opening in a body lumen. Toy further discloses a third element (24; also including a distal end is that is slanted with respect to the center line of the device) that could be used as a guiding member. The use of the device disclosed in prior art does not have to be exactly the same as in the present invention, so long as the structure of the device can perform the claimed tasks.

Regarding claim 10, Nichols as modified above discloses the tubular member and the guiding member made of a variety of materials (column 1, lines 34-50), but fails to specifically disclose the guiding member made of a resin material harder than that of the tubular member.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the guiding member of a resin material harder than that of the tubular member, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

6. **Claims 11 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Nichols (US 3,088,466)** in view of **Jones (US 4,278,081) and Toy (US 3,511,243)** further in view of **Simonson (US 2003/0083688).**

Regarding claims 11 and 12, Nichols as modified above discloses the invention substantially as claimed above, including the first and second guiding members being tubular (Toy, Figures 7-9), and the first guiding member having a diameter smaller than the diameter of the tubular member (Nichols; Figure 5), but fails to disclose the second guiding member having a diameter that is smaller than the first guiding member.

However, Simonson teaches a series of guiding members and a tubular member, wherein the second guiding member (16) has a diameter that is smaller than that of the first guiding member (12), and the first guiding member has a diameter that is smaller than the tubular member (30; Figure 2), wherein the second guiding member is configured to guide the first tubular member, said first tubular member includes a

second guiding member first alignment mark (24), and said second tubular member including a second guiding member second alignment mark (24) such that with the second guiding member first alignment mark aligned with the second, the digestive organ end of the first guiding member is generally coincident with a digestive organ end of the second guiding member (Figure 3; the tool alignment marks are axially aligned and provide for the digestive organ end of the tubular member and guiding members to be coincident).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the tubular and guiding members disclosed by Nichols in view of Jones and Toy have diameters that are decreased from the largest tubular member, to the medium first guiding member to the smallest second guiding member as taught by Simonson as such a modification would provide a gradual dilation of the tissue being contacted by the dilators and allow for access to the internal organs of a patient.

Response to Arguments

In response to applicant's argument that the prior art is used in a trachea while the present invention is to be used in a pharynx, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The way the devices of the prior art are described as being used in their respective disclosures does not disqualify the devices of the prior art from being manipulated to be used in the way described in the present invention. The structures disclosed in Nichols, Jones and Toy can be used in a manner as described in the currently presented claims. It is acknowledged that the methods of use of the device of the present invention and the prior art differ, however, the claims currently presented are drawn to the invention of the apparatus, thus the manner in which the devices are used is not the subject matter being examined. The curved shape of the devices of Nichols, Jones and Toy, as well as the compliant nature of the materials of which the devices are made provides for a device that conforms to the shape of a pharynx. The similar tubular anatomy of the pharynx and trachea allows for devices to be used interchangeably between the two locations. The claims simply call for the member to be curved to conform to the shape of a pharynx, but does not detail give details of the curvature of the device. Thus, the devices disclosed by Nichols, Jones and Toy could be used conform to and traverse the pharyngeal opening.

Regarding the ability for the guiding member of Nichols to be placed prior to the tubular member, Nichols discloses the guiding member being removed from the cavity and the tubular member remaining therein (column 4, lines 48-56). The nature of the materials used by Nichols allows for the tubular member to be tracked over the guiding tube. Nichols discusses that the materials possess resilience (column 3, lines 69-72) and the thickness and the spacing between the tubes can be varied. The applicant argues that the diameter of the guiding tube (3) of Nichols is smaller than that of the

tubular member (1), and thus insertion of the tubular member over the guiding member would not be allowed. However, the smaller diameter of the guiding tube is precisely why the tubular member would be able to pass over the guiding member.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Szpira whose telephone number is (571) 270-3866. The examiner can normally be reached on Monday-Friday, 10AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to:

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./
Examiner, Art Unit 3731
April 10, 2012

/S. Thomas Hughes/
Supervisory Patent Examiner, Art Unit 3731